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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,540	09/22/2003	Lawrence M. Boyd	1842-0024	9957
28078	7590	07/26/2007	EXAMINER	
MAGINOT, MOORE & BECK, LLP			PHILOGENE, PEDRO	
CHASE TOWER			ART UNIT	PAPER NUMBER
111 MONUMENT CIRCLE			3733	
SUITE 3250				
INDIANAPOLIS, IN 46204				

  

MAIL DATE	DELIVERY MODE
07/26/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/667,540	BOYD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Pedro Philogene	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1)  Responsive to communication(s) filed on 14 May 2007.
- 2a)  This action is **FINAL**.                                    2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4)  Claim(s) 34-40, 42-47, 49, 51-65, 69-72 and 80-96 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 34-40, 42-47, 51-65, 69-72, 80-96 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some \* c)  None of:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5)  Notice of Informal Patent Application
- 6)  Other: \_\_\_\_\_.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 34-40,42-47,49,51-65,69-72,80-96 are rejected under 35 U.S.C. 102(b) as being anticipated by Wardlaw (6,402,784).

Wardlaw discloses a kit of parts and a device for sealably introducing fluent material directly into a disc space through an opening (58) extending through the annulus fibrosis of the disc comprising: a seal (16) for cooperatively engaging the annulus fibrosis adjacent the opening (58) for sealing the opening, tube (30) having a passageway (40) for the flow of fluent material (14) therethrough and an extent (syringe) adapted to be received in the opening of the annulus fibrosis; as set forth in column 10, lines 48-64; the tube being configured for cooperative sealed engagement through the seal; and a vent (24) extending through the seal in sealed engagement therewith and in direct communication with the disc space when the seal engagement engages the annulus fibrosis, a tube having a passage way (40) for the flow of fluent material therethrough and an extent (the tip of the syringe) adapted to be received in the opening of the annulus fibrosis, the tube (30) having a seal (16) adapted to engage said annulus fibrosis adjacent the opening and to form a fluid-tight seal therewith; and a quantity of

curable fluent material (14) adapted to be introduced in a fluid state into the disc space through the passageway of the tube, the material upon curing having properties substitutive of the nucleus pulposus; as set forth in column 3, lines 30-67, column 4, lines 1-65, column 5, lines 1-67, column 6, lines 35-67, column 9, lines 1-67, column 10, lines 49-63; and as best seen in FIGS.1-8.

With respect to the method claims, the method steps, as set forth, would have been inherently carried out in the operation of the device, as set forth above. The method steps, such as, creating an opening through the disc annulus fibrosis; as best seen in FIG.4B, distracting the vertebral bodies apart to increase disc height, FIG.7A; sealably introducing under pressure a curable biomaterial having properties substitutive of nucleus pulposus when cured through the opening contiguously into the intradiscal space until the intradiscal space is substantially filled; as set forth in column 3, lines 30-67, column 4, lines 1-65, column 5, lines 1-67, column 6, lines 35-67, column 9, lines 1-67, column 10, lines 49-63; and as best seen in FIGS.1-8.

***Response to Amendment***

Applicant's arguments, see Remarks, filed 5/14/07, with respect to the rejection(s) of claim(s) 34-40,42-47, 49, 51-65, 69-72, 80-96 under 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Wardlaw.

***Conclusion***

A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pedro Philogene  
July 7, 2007

  
PEDRO PHILogene  
PRIMARY EXAMINER